UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,108	08/22/2003	Meir Rosenberg	022719-0045	8437

21125 7590 06/22/2007

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	**PAPER NUMBER**
3736	

MAIL DATE	DELIVERY MODE
06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,108	ROSENBERG, MEIR	
	Examiner	Art Unit	
	Helen Nguyen	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 3/23/2007. Claim 6 is amended, overcoming the previous claim objection. **Claims 1-4 and 6-33** remain pending

Claim Objections

2. **Claims 7-8** are objected to because of the following informalities: said claims depend upon Claim 5, which has previously been cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claims 1-4, 6, 9-10, 21-24 and 28-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodin et al (4928693) in view of Bobo, Sr. (5573007).

6. **Claims 7, 25, and 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodin et al as modified by Bob, Sr, further in view of Goldstein et al. (5899937).

7. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodin et al as modified by Bobo, Sr, further in view of Fiddian-Green (5174290).

8. **Claims 11-13, 16-20, 26-27, and 32-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodin et al as modified by Bobo, Sr, further in view of Brockway et al (4846191).

9. **Claim 14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodin et al as modified by Bobo, Sr, further in view of Sgourakes (4638656).

10. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable Goodin et al as modified by Bobo, Sr, further in view of Wallace et al (5951497).

11. Please refer to the Office Action dated 12/28/2006 for further details.

Response to Arguments

12. Applicant's arguments filed 3/23/2007 have been fully considered but they are not persuasive. Applicant contends that modifying Goodin to include a flexible membrane disposed across the second fluid-filled lumen will "render the device inoperable for its intended use" (remarks p.7), citing a portion of the reference that describes an embodiment comprising two lumens, one "exiting the distal end of the catheter" and the other having a port "extending through the wall of the catheter" as evidence that Goodin desire that the lumens remain unsealed. However, while it is noted that as described in the embodiment of Figures 1-4, lumen 18 is not sealed at its distal end to allow passage of guidewire 38, which would correspond to the above lumen "exiting the distal end of the catheter," the more ambiguous language used to describe the other lumen with a port "extending through the wall of the catheter" does not necessarily suggest to one of ordinary skill in the art that the second lumen 20 is also likewise unsealed. It is noted that the broadest reasonable definition of "sealed" is simply "closed, secured, or covered with"

(www.dictionary.com). By that definition, the lumen is considered sealed by a covering placed anywhere along its length, such as on the distal end. In that regard, the disclosure of the lumen with a port "extending through the wall of the catheter" does not necessarily suggest to one of ordinary skill in the art that the distal end of said lumen is open or unsealed. For example, the port could extend through a *side* wall of the catheter and still be sealed at its distal end.

13. In fact, Goodin highly suggests that such a seal is present at the distal end of lumen 20 for the purpose of allowing the blood pressure existing at said location to be transmitted through the fluid in the lumen to the proximal end and subsequently, to the blood pressure measuring equipment (Col.4: 19-24). The blood pressure existing at the distal end cannot be transmitted for measurement without an indication means, i.e. a covering on the distal end of lumen 20. Thus, the distal end 14 of lumen 20 must be sealed to properly enable blood pressure transmission. While Applicant states that "it is possible for the distal end of the lumen to remain open to receive blood flow therethrough" because "fluid could be added during the procedure to eliminate the need for blood to flow through the entire length of the catheter, and/or prevent blood from flowing into the external blood pressure measuring equipment" (remarks p.8), one of ordinary skill would be highly inclined to believe otherwise. Goodin clearly discloses lumen 20 filled with an incompressible fluid for blood pressure measurement, thus invalidating any desire or need for the lumen to remain unsealed to allow blood flow therethrough, for pressure measurement or any reasons otherwise. Furthermore, it is obvious to one of ordinary skill in the art that an unsealed lumen would allow the incompressible fluid in lumen 20 to undesirably leak into the blood stream of the patient as well as introduce undesired matter into the catheter. It is also commonly known throughout the art that blood pressure measurement means that utilize a

fluid to transmit the blood pressure have a sealed portion comprising a flexible material for the transmission process. For example, Brockway et al as used in the above rejection teaches a gel 30 at the distal tip of pressure measurement device to retain fluid 29 used for transmission of pressure to pressure transducer 16 (Col.5: 40-57). Thus, Applicant has not shown that the addition of a flexible membrane to Goodin would render the device inoperable. Rather, as elaborated above, all teachings of Goodin highly suggest that a flexible membrane would not only be in line with the device, but also advantageously enhance the blood pressure measurement means described therein.

14. Applicant also contends that the Examiner has failed to provide motivation for the desirability of the addition of the flexible membrane. However, as just described above, the flexible membrane necessarily allows the transmission of the blood pressure through the fluid-filled lumen and is thus desirable. Lastly, Applicant contends that "it is not possible to add the pressure sensor to the Goodin device without significantly modifying the device" (remarks p.8) as Goodin does not expressly teach a catheter with a pressure sensor. While the Examiner agrees that Goodin appear to teach a pressure sensor as part of an external measuring equipment, it would be quite obvious to one of ordinary skill in the art to modify the catheter to include a pressure sensor within for the same purpose of pressure sensing while enhancing the portability and compactness of the overall device without disadvantageously teaching away. Therefore, the Examiner submits that the combination of Goodin in view of Bobo, Sr as explained above and in the previous Office Action teach a catheter comprising a first lumen, a second sealed lumen filled with an incompressible fluid extending between a flexible membrane disposed across an opening formed in the catheter and that is adapted to be exposed to an external pressure source,

and a pressure sensor that is effective to measure pressure of the external pressure source as claimed.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
6/18/2007

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700